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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,223	07/30/2003	Francis Michon	20695C-001410US	8301

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,223	MICHON ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction / Species Election

1) Claims 1-51 are under prosecution.

2) Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 6-11 and 44-46, drawn to a multivalent conjugate molecule comprising a carrier protein covalently conjugated to GBS type Ia, type III, and type V capsular polysaccharides, or at least three GBS capsular polysaccharides selected from the group consisting of types Ia, Ib, II, III, V and VIII, classified in class 424, subclass 197.1

II. Claims 13-16 and 47-51, drawn to a multivalent conjugate molecule comprising a carrier protein covalently conjugated to the B, C and Y *N. meningitidis* capsular polysaccharides; the C, Y and W-135 *N. meningitidis* capsular polysaccharides; or to at least three *N. meningitidis* capsular polysaccharides selected from the group consisting of A, B, C, W and Y, classified in class 424, subclass 197.1

III. Claims 22-26, drawn to a method of preparing a multivalent conjugate molecule comprising a carrier protein covalently conjugated to GBS type Ia, type III, and type V capsular polysaccharides, or at least three GBS capsular polysaccharides selected from the group consisting of types Ia, Ib, II, III, V and VIII, classified in class 536, subclass 124

IV. Claims 27-31, drawn to a method of preparing a multivalent conjugate molecule comprising a carrier protein covalently conjugated to the B, C and Y *N. meningitidis* capsular polysaccharides, to the C, Y and W-135 *N. meningitidis* capsular polysaccharides, or to at least three *N. meningitidis* capsular polysaccharides selected from the group consisting of A, B, C, W and Y, classified in class 536, subclass 124

V. Claims 34-36, drawn to a method of preventing or attenuating GBS infection comprising administering to a mammal a multivalent conjugate comprising a carrier protein conjugated to GBS type Ia, type III, and type V capsular polysaccharides, or at least three GBS capsular polysaccharides selected from the group consisting of types Ia, Ib, II, III, V and VIII, classified in class 424, subclass 244.1

VI. Claims 37-41, drawn to a method of preventing or attenuating *N. meningitidis* infection comprising administering to a mammal a multivalent conjugate comprising a carrier protein conjugated to B, C and Y *N. meningitidis* capsular polysaccharides;

the C, Y and W-135 *N. meningitidis* capsular polysaccharides; or to at least three *N. meningitidis* capsular polysaccharides selected from the group consisting of A, B, C, W and Y, classified in class 424, subclass 249.1

Claims 1-5, 12, 15, 42 and 43 are considered as linking claims and would be joined with one of inventions I and II, if elected.

Claims 17-21 are considered as linking claims and would be joined with one of inventions II and III, if elected.

Claims 32 and 33 are considered to be linking claims and would be joined with one of inventions V and VI, if elected.

3) Inventions I-VI are distinct from one another for the following reasons. Inventions I and II are drawn to two divergent products: a multivalent conjugate comprising GBS capsular polysaccharides, and a multivalent conjugate comprising *N. meningitidis* capsular polysaccharides, which are distinct from one another in their structure, immunospecificity, and functions. Furthermore, the structurally distinct polysaccharides of GBS types Ia, Ib, II, III, V and VIII, the structurally distinct polysaccharides of A, B, C, W135 and Y *N. meningitidis* capsular polysaccharides require separate individual structural searches. Searching inventions I and II together would impose a serious search burden, since searches are non-coextensive. There is also search burden with regard to the non-patent literature.

4) Inventions III, IV, V and VI are drawn to distinct methods, which differ from one another in the product or reagent used therein, methods steps and parameters, and method objectives. The products used in these methods are structurally distinct molecules, each requiring separate and non-coextensive searches. Therefore, searching the above-identified inventions together would not be coextensive and thus impose a serious search burden.

5) Inventions I and V, and inventions II and VI, are related as product and process of use of the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the product of inventions I and II can be used in a materially different process, for example, an *in vitro* technique as a reagent for purification of respective GBS or meningococcal capsular-specific antibody mixtures.

Searching the inventions of inventions I and V, and inventions II and VI, would impose a serious search burden. These inventions have a separate status in the art as shown by their different classifications. The search for these inventions would require a text search for the claimed methods in addition to a search for each product. Moreover, even if each product were known, the methods, which use the products, may be novel and unobvious in view of the preamble or active steps.

6) Inventions I and III, and inventions II and IV are related as product and process of making the product. The inventions are distinct if either or both of the following can be shown: (1) that the processes as claimed can be used to make other and materially different products or (2) that the products as claimed can be made by another and materially different processes (MPEP 806.05(f)). In the instant case, the conjugate of inventions I or II can be made by a process materially different from the process of invention III or IV, for example, by chemical synthesis or recombinant expression or fusion.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, and because the search required for each group is not required for the other groups since each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

7) The Office has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

8) In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See 'Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)', 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.* Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

10) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

11) If invention I, III or V is elected, Applicants must further elect one of the specific multivalent GBS conjugate species: (a) type Ia, type III and type V of claims 7 and 45, claim 23 or 35; and (b) a specific multivalent conjugate species in claims 6 and 44, claim 22 or 34. Claims 1-5. 42, and 43, claims 17-21, and claims 32 and 33 are generic.

If invention II, IV or VI is elected, Applicants must further elect one of the specific multivalent meningococcal conjugate species: (a) B, C and Y of claims 13 and 48; (b) C, Y and W-135 of claims 14 and 49; and (c) a specific multivalent conjugate species in claims 12 and 47, claim 27 or 37. Claims 1-5, 42 and 43, claims 17-21, claims 32 and 33 are generic.

12) In addition to electing one of the species as indicated above, Applicants must further elect one of the carrier protein species of claims 5, 8, 15, 16, 21, 24, 30, 31, 33, 36, 40, 41, 43, 46, 50 and 51: (a) C alpha; (b) C beta; (c) tetanus toxoid; (d) diphtheria toxoid; (e) CRM197; and (f) porin protein. Claims 1-4, 6, 7-14, 17-20, 22, 23, 25-29, 32, 34, 35, 37-39, 42, 44, 45 and 47-49 are generic.

Applicants are required under 35 U.S.C 121 to elect a single disclosed species, even though this requirement is traversed.

13) Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other invention.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Central Fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

15) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

May, 2006

S. DEVI, PH.D.
PRIMARY EXAMINER